11.08.00

Please type a plus sign (+) inside this box → [+]

PTO/SB/05 (4/98)
Approved for use through 09/30/2000. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1 53(b))

| | |
|---|---|
| Attorney Docket No. | INS-31061-A |
| First Inventor or Application Identifier | Alan R. Hirsch |
| Title | See 1 in Addendum |
| Express Mail Label No | EL587909762US |

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)*
*(Submit an original and a duplicate for fee processing)*

2. [X] Specification [Total Pages 24 ]
*(preferred arrangement set forth below)*
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [ ] Drawing(s) *(35 U.S.C. 113)* [Total Sheets [ ]]

4. Oath or Declaration [Total Pages 3 ]
a. [ ] Newly executed (original or copy)
b. [X] Copy from a prior application (37 C F.R § 1 63(d))
*(for continuation/divisional with Box 16 completed)*
i [ ] DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

** NOTE FOR ITEMS 1 & 13 IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R § 1.28).*

5. [ ] Microfiche Computer Program *(Appendix)*

6. Nucleotide and/or Amino Acid Sequence Submission
*(if applicable, all necessary)*
a. [ ] Computer Readable Copy
b. [ ] Paper Copy (identical to computer copy)
c. [ ] Statement verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C F R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [X] Information Disclosure Statement (IDS)/PTO-1449 [X] Copies of IDS Citations
11. [X] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503)
*(Should be specifically itemized)*
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [X] Statement filed in prior application Status still proper and desired
14. [ ] Certified Copy of Priority Document(s)
*(if foreign priority is claimed)*
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*
[ ] Continuation [X] Divisional [ ] Continuation-in-part (CIP) of prior application No: 09/211,507
*Prior application information:* Examiner C. Tate Group / Art Unit: 3736

**For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.**

## 17. CORRESPONDENCE ADDRESS

[X] *Customer Number or Bar Code Label* **022202** *(Insert Customer No. or Attach bar code label here)* or [ ] *Correspondence address below*

| | | | | | |
|---|---|---|---|---|---|
| Name | PATENT AND TRADEMARK OFFICE | | | | |
| Address | | | | | |
| City | | State | | Zip Code | |
| Country | | Telephone | | Fax | |

| | | | |
|---|---|---|---|
| Name (Print/Type) | Kristine M. Strodthoff | Registration No. (Attorney/Agent) | 34259 |
| Signature | Kristine M Strodthoff | Date | 07 NOV 2000 |

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

# Attachment to PTO/SB/05 (4/98) Utility Patent Application Transmittal

1. Use of Odorants to Alter Vaginal Blood Flow, and Article of Manufature Therefor

PTO/SB/17 (12/99)
Approved for use through 09/30/2000 OMB 0651-0032
Patent and Trademark Office. U S DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

# FEE TRANSMITTAL for FY 2000

*Patent fees are subject to annual revision*
*Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid See Forms PTO/SB/09-12*
*See 37 C F R §§ 1 27 and 1 28*

**TOTAL AMOUNT OF PAYMENT** ($) 400.00

| Complete if Known | |
|---|---|
| Application Number | |
| Filing Date | |
| First Named Inventor | Alan R. Hirsch |
| Examiner Name | C. Tate |
| Group / Art Unit | 3736 |
| Attorney Docket No. | INS-31061-A |

## METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authonzed to charge indicated fees and credit any overpayments to

Deposit Account Number

Deposit Account Name

☐ Charge Any Additional Fee Required Under 37 CFR §§ 1 16 and 1 17

2. ☒ **Payment Enclosed:**
☒ Check ☐ Money Order ☐ Other

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 101 | 690 | 201 | 345 | Utility filing fee | 355.00 |
| 106 | 310 | 206 | 155 | Design filing fee | |
| 107 | 480 | 207 | 240 | Plant filing fee | |
| 108 | 690 | 208 | 345 | Reissue filing fee | |
| 114 | 150 | 214 | 75 | Provisional filing fee | |

SUBTOTAL (1) ($) 355.00

### 2. EXTRA CLAIM FEES

| | | Extra Claims | | Fee from below | Fee Paid |
|---|---|---|---|---|---|
| Total Claims | 25 | -20** = 5 | X | 9 | = 45 |
| Independent Claims | 3 | - 3** = 0 | X | 40 | = 0 |
| Multiple Dependent | | | | | = 0 |

***or number previously paid, if greater; For Reissues, see below*

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 103 | 18 | 203 | 9 | Claims in excess of 20 |
| 102 | 78 | 202 | 39 | Independent claims in excess of 3 |
| 104 | 260 | 204 | 130 | Multiple dependent claim, if not paid |
| 109 | 78 | 209 | 39 | ** Reissue independent claims over original patent |
| 110 | 18 | 210 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) ($) 45.00

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 105 | 130 | 205 | 65 | Surcharge - late filing fee or oath | 0.00 |
| 127 | 50 | 227 | 25 | Surcharge - late provisional filing fee or cover sheet | 0.00 |
| 139 | 130 | 139 | 130 | Non-English specification | 0.00 |
| 147 | 2,520 | 147 | 2,520 | For filing a request for reexamination | 0.00 |
| 112 | 920* | 112 | 920* | Requesting publication of SIR prior to Examiner action | 0.00 |
| 113 | 1,840* | 113 | 1,840* | Requesting publication of SIR after Examiner action | 0.00 |
| 115 | 110 | 215 | 55 | Extension for reply within first month | 0.00 |
| 116 | 380 | 216 | 190 | Extension for reply within second month | 0.00 |
| 117 | 870 | 217 | 435 | Extension for reply within third month | 0.00 |
| 118 | 1,360 | 218 | 680 | Extension for reply within fourth month | 0.00 |
| 128 | 1,850 | 228 | 925 | Extension for reply within fifth month | 0.00 |
| 119 | 300 | 219 | 150 | Notice of Appeal | 0.00 |
| 120 | 300 | 220 | 150 | Filing a brief in support of an appeal | 0.00 |
| 121 | 260 | 221 | 130 | Request for oral hearing | 0.00 |
| 138 | 1,510 | 138 | 1,510 | Petition to institute a public use proceeding | 0.00 |
| 140 | 110 | 240 | 55 | Petition to revive - unavoidable | 0.00 |
| 141 | 1,210 | 241 | 605 | Petition to revive - unintentional | 0.00 |
| 142 | 1,210 | 242 | 605 | Utility issue fee (or reissue) | 0.00 |
| 143 | 430 | 243 | 215 | Design issue fee | 0.00 |
| 144 | 580 | 244 | 290 | Plant issue fee | 0.00 |
| 122 | 130 | 122 | 130 | Petitions to the Commissioner | 0.00 |
| 123 | 50 | 123 | 50 | Petitions related to provisional applications | 0.00 |
| 126 | 240 | 126 | 240 | Submission of Information Disclosure Stmt | 0.00 |
| 581 | 40 | 581 | 40 | Recording each patent assignment per property (times number of properties) | 0.00 |
| 146 | 690 | 246 | 345 | Filing a submission after final rejection (37 CFR § 1 129(a)) | 0.00 |
| 149 | 690 | 249 | 345 | For each additional invention to be examined (37 CFR § 1 129(b)) | 0.00 |
| Other fee (specify) | | | | | 0.00 |
| Other fee (specify) | | | | | 0.00 |

* Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 0.00

| SUBMITTED BY | | | | Complete (if applicable) | |
|---|---|---|---|---|---|
| Name (Print/Type) | Kristine M. Strodthoff | Registration No (Attorney/Agent) | 34259 | Telephone | 414-273-2100 |
| Signature | Kristine M Strodthoff | | | Date | 07 NOV 2000 |

**WARNING:**

**Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

Burden Hour Statement This form is estimated to take 0 2 hours to complete Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO Assistant Commissioner for Patents, Washington, DC 20231

Attorney's Docket No.: 054012-0009 PATENT

Applicant: Alan R. Hirsch

Serial or Patent No.: 09/211,507

Filed: December 14, 1998

For: USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS 37 CFR 1.9(f) and 1.27(b))-INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled : USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR , described in U.S. patent application Serial No. 09/211,507, filed December 14, 1998 .

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[ X ] no such person, concern, or organization

[ ] persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

FULL NAME: _____

ADDRESS: _____.

[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Alan R. Hirsch (Name of inventor)

845 N. Michigan Ave Chicago, IL. (Address)

(Signature of Inventor) Date: 2/9/99

MW300431_1

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of : Alan R. Hirsch

Serial No. : Unknown (Divisional of USSN 09/211,507)

Filing Date : Herewith

For : USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR

Attorney Docket No. : INS-31061-A

---

**CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10**

I hereby certify that, on the date shown below, this correspondence is being:

**Mailing**

● deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, Box Patent Application

**37 CFR 1.8(a)**

☐ with sufficient postage as first class mail

**37 CFR 1.10**

● As "Express Mail Post Office to Addressee" Mailing Label No. EL587909762US

**Transmission**

☐ transmitted by facsimile to Fax No_____ addressed to Examiner_____ at the Patent and Trademark Office.

Date: 11.7.00 Jan R. Hauk

---

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

**COMMUNICATION AND PRELIMINARY AMENDMENT**

Sir:

This application is a divisional of U.S. Serial No. 09/211,507. **Prior to calculating the filing fee, please cancel Claims 2-23.**

**Preliminary Amendment**

Prior to substantive examination, Applicant requests the following amendments be made in this application.

**IN THE CLAIMS**

Claims 2-23 have been cancelled in the filing of this divisional application, Please cancel Claim 1, and add new Claims 24- 48, as follows.

24. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to alter vaginal blood flow when inhaled by a female individual; and

instructions for administering the odorant to alter vaginal blood flow.

25. The article of manufacture according to Claim 24, further comprising at least one of the following:

a device for measuring vaginal blood flow of the female individual; and

means for testing olfactory ability in the female individual.

26. The article of manufacture of Claim 24, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.

27. The article of manufacture of Claim 24, wherein the concentration of the odorant is at about 25-55 decismel units.

28. The article of manufacture of Claim 24, wherein the odorant is packaged within a delivery device selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.

29. The article of manufacture of Claim 24, wherein the odorant is in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.

30. The article of manufacture of Claim 24, wherein the odorant is in the form of a cream or a cologne.

31. The article of manufacture of Claim 24, wherein the odorant is in a liquid form contained in a dispenser.

32. The article of manufacture of Claim 31, wherein the dispenser has a tip impregnated with the odorant.

33. The article of manufacture of Claim 32, wherein the dispenser contains the odorant absorbed to a wicking material.

34. The article of manufacture of Claim 24, wherein the odorant is selected from the group consisting of a baby powder odorant, a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a floral-aldehydic perfume odorant, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants.

35. The article of manufacture of Claim 24, wherein the odorant comprises a mixture of a licorice-based and cucumber odorant.

36. The article of manufacture of Claim 24, wherein the unit dosage amount of the odorant is effective to increase vaginal blood flow of the female individual by about 10-30%.

37. The article of manufacture of Claim 36, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a baby powder odorant, a mixture of a lavender and pumpkin pie odorant, and a mixture of a baby powder and chocolate odorant.

38. The article of manufacture of Claim 24, wherein the unit dosage amount of the odorant is to decrease vaginal blood flow of the female individual by about 10-20%.

39. The article of manufacture of Claim 38, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, a mixture of licorice-based and cucumber odorants, and a floral-aldehydic perfume odorants.

40. The article of manufacture of Claim 38, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.

41. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to increase vaginal blood flow when inhaled by a female individual; and

instructions for administering the odorant to increase vaginal blood flow.

42. The article of manufacture of Claim 41, wherein the unit dosage amount of the odorant is effective to increase vaginal blood flow of the female individual by about 10-30%.

43. The article of manufacture of Claim 41, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a baby powder odorant, a mixture of a lavender and pumpkin pie odorant, and a mixture of a baby powder and chocolate odorant.

44. The article of manufacture of Claim 41, wherein the odorant comprises a mixture of a licorice-based and cucumber odorant.

45. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to decrease vaginal blood flow when inhaled by a female individual; and

instructions for administering the odorant to decrease vaginal blood flow.

46. The article of manufacture of Claim 45, wherein the unit dosage amount of the odorant is to decrease vaginal blood flow of the female individual by about 10-20%.

47. The article of manufacture of Claim 45, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, a mixture of licorice-based and cucumber odorants, and a floral-aldehydic perfume odorants.

48. The article of manufacture of Claim 45, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.



**IN THE SPECIFICATION**

Please amend the specification as follows.

At page 1, line 5 (Cross-Reference to Related Applications), after "This application" insert —is a divisional of U.S. Patent Application Serial No. 09/211,507, filed December 14, 1998, and--.

**REMARKS**

Consideration of the newly added and pending Claims 24-48 is requested. Support for the claims is in the original claims as filed, and in the specification at page 7, lines 17-18 (unit dosage amount).

It is respectfully submitted that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is urged to telephone the undersigned attorney if any questions should arise.

Respectfully submitted,

Kristine M. Strodthoff
Registration No. 34,259

Dated: November 7, 2000

P.O. ADDRESS:
WHYTE HIRSCHBOECK DUDEK S.C.
111 East Wisconsin Avenue, Suite 2100
Milwaukee, Wisconsin 53202
(414) 273-2100
Customer No. 022202

# USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application Serial No. 60/069,460, filed December 15, 1997.

## BACKGROUND OF THE INVENTION

Various researchers have focused attention on odors and their connection with sexuality. Almost a hundred years ago, Sigmund Freud was concerned that if the sense of smell was not repressed, men -- but not necessarily women -- would walk around sexually excited all the time. Freud also linked odor with the Oedipal conflict when he said that during a boy's development, he learns to recognize the odor of both parents, and eventually he comes to dislike the father's odors and have positive associations with the mother's odors. Although Freud also spoke of the Electra Complex, a corresponding development conflict in girls, he made no mention of the significance of the parent's odors in female psychological maturation.

In men, an erection occurs when increased blood flow to the penis causes spongelike chambers to become engorged as the blood vessels of the penis expand. In women, arousal causes increased blood flow to the vagina, which expands the vaginal tissues and stimulates the release of lubricating fluids along the walls of the vagina. The clitoris becomes engorged during the arousal phase because of increased blood flow to the region.

Sexual dissatisfaction is common among married couples in our society, and arousal disorders are a very common form of sexual dysfunction. In the early 1950s, a survey by sex researcher Alfred Kinsey found that 10 percent of married women never experienced coital orgasm. (Kinsey et al., *Sexual Behavior in the Human Female*, Philadelphia: W.B. Saunders (1953)). In 1956, a British study of 3,705 women

reported that 10 percent of women rarely experienced orgasm and another 5 percent never experienced orgasm during intercourse. (E. Chesser, *The Sexual Marital and Family Relationships of the English* Woman, London: Hutchinson's Medical Publications (1956)). In the 1970s, a study in the United States reported 17 percent of women seen at a gynecologic clinic stated that they had difficulty achieving orgasm with a partner, and 6 percent had never experienced orgasm with a partner. (E. Frank et al., *N. Engl. J. Medicine* 299:111 (July 20, 1978)).

Research into olfactory-related sexual behavior has been documented in laboratory animals. Pheromones, which are chemical substances produced by an organism for purposes of chemo-communication with another of the same species, have been documented in many animals. Pheromones are not consciously recognized by the brain but influence hormone production, and sexual attraction, drive and even behavior. Although pheromones exist throughout the animal kingdom, it is not known for certain that human pheromones exist. One postulated human pheromone system concerns menstruation. It has been observed that women who live in close contact with one another menstruate together. Another system involves the steroid androsterone which has been named as a pheromone that is secreted from the apocrine glands located in the underarm area and around the genital organs. Androsterone has been found to have an attractant effect on women and an aversive effect on men. Alternate theories suggest that what we call potential pheromones are simply odors associated with sex, and human response to them is conditioned.

There has been other research into the olfactory-sexual link. When the olfactory bulb was lesioned in hamsters, it caused an impaired sex drive. An olfactory-sexual connection has also been observed in laboratory animals that were castrated. The castration led to both impaired sexual drive and olfactory functioning. Ovariectomies led to both impaired sexual functioning and reduced olfactory ability. Lesions of the olfactory bulb or of the nasal cartilage alone, caused both an olfactory deficit and a malformation of the developing animal's sex organs. These studies indicate a link between olfaction, olfactory organs and sexual functioning.

The linkage between olfactory function and sexual function has also been recognized in a clinical setting. Over 17% of individuals with chemosensory dysfunction who develop impaired sexual desire or other sexual dysfunction, (i.e., Kallmann's syndrome), have both an olfactory deficit and impaired sexual drive and functioning. (Kallmann, F.J., Schoefeld, W.A., and Barrera, S.E., "The genetic aspects of primary eunuchoidism," *Am. J. Mental Deficiency* 48:203-236 (1944)). Other diseases that impair both olfactory ability and sexual functioning concomitantly include cerebral vascular disorders, Parkinson's disease, senile dementia of the Alzheimer's type, hypothyroidism, and vitamin deficiency states including B12 deficiency.

Treatment of a repressed or overly stimulated sex drive can include counseling directed toward dealing with insecurities and enhancing feelings of affection and receptiveness, or reducing sexual aggressiveness. Treatments for enhancing or inhibiting female sexual capacity and response include medications such as vaginal lubricants, or psychotherapy, group therapy, cognitive therapy or behavior therapy. However, such treatments have not been totally effective, are invasive can cause unwanted side effects, and are inconvenient and complex.

Therefore, an object of the invention is to provide a non-invasive method of enhancing or inhibiting the female sexual response and arousal level, that is convenient, safe, and easy to perform.

## SUMMARY OF THE INVENTION

These and other objects are achieved in a non-invasive method of altering vaginal blood flow in a female individual to augment or lessen sexual arousal. The method involves administering an amount of an odorant or odorant mixture for inhalation that is sufficient to alter vaginal blood flow of the female by about -20% to about +30% compared to blood flow without being given the odorant. Also provided is a method for screening an odorant for its effect in increasing or decreasing vaginal

blood flow, and a kit, or article of manufacture, containing a odorant and instructions for its use in altering vaginal blood flow.

## DETAILED DESCRIPTION OF THE INVENTION

In one embodiment of the invention, the odorant can be administered in an amount sufficient to increase vaginal blood flow of the female individual. By increasing vaginal blood flow, the female individual will experience increased or enhanced sexual arousal. Examples of odorants and odorant mixture that can be administered to increase vaginal blood flow by about 10-30%, include a baby powder odorant, a mixture of licorice-based odorant and banana nut bread odorant, a mixture of a licorice-based odorant and cucumber odorant, a floral-aldehydic perfume fragrance such as Chanel No. 5 and White Linen, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants. Examples of licorice-based odorants include a black licorice odorant, and Good N' Plenty® (licorice and anise) odorant. Such odorants are commercially available, for example, from International Flavors and Fragrances, Inc. (IFF, New York, NY), Energy Essentials, AromaTech, Inc. (Somerville, NJ), Florasynth, Inc. (Teterboro, NJ), and as essential oils. Such individual odorants and odorant mixtures have been found to be particularly useful in increasing vaginal blood flow in female individuals who are highly aroused by masturbation.

According to the invention, odorants can also be administered to decrease vaginal blood flow of a female individual. With a reduction in vaginal blood flow, the female individual experiences an inhibited or reduced level of sexual arousal. Examples of odorants and odorant mixture that can be administered to decrease vaginal blood flow by about 10-20% include a licorice-based odorant alone, a mixture of a licorice-based odorant and cucumber odorant, a cologne such as Old Spice®, a floral-aldehydic perfume fragrance such as Chanel No. 5 and White Linen, a charcoal barbecue meat odorant, and a cherry odorant. Such odorants and odorant mixtures have been found to be

particularly useful in reducing vaginal blood flow in female individuals who are minimally or not highly sexually aroused by masturbation or manual manipulation of the female genitals.

In the use of odorants to stimulate or decrease vaginal flow, it is preferred that the subject individual is presented with the odorant at a suprathreshold concentration (e.g., about 25-55 decismel units), but not irritative level, and inhales the odorant for about 1-3 minutes.

An odorant is presented at a suprathreshold level when the decismel level or concentration of the odorant is beyond that needed to be detected by a normosmic individual. At its irritative level, the odorant quantity is so high and intense that the odorant stimulates predominantly the trigeminal nerve (for pain) rather than the olfactory nerve and, hence, is perceived as noxious or painful. The irritation threshold of the patient is the lowest concentration of the substance that causes immediate stinging or burning sensations in the nose, or stinging or lacrimation of the eye. See, J.F. Gent, in *Clinical Measurement of Taste and Smell*, pages 107-166, H.L. Meiselman et al. (eds.), 602 pp., MacMillan, NY (1986); R.L. Doty et al., *Ann. Neurol.* 25: 166-171 (1989); E. Koss et al., *Neurology* 38: 1228-1232 (1988); and R. Doty, *The Smell Identification Test: Administration Manual* 1983: 13-14, Philadelphia: Sensonics, Inc. (1983).

Preferably, prior to the administration of the odorant, the individual undergoes olfactory testing according to a test such as the University of Pennsylvania Smell Identification Test (UPSIT), a 40-question forced-choice, scratch-and-sniff identification test, and the Chicago Smell Test, a 3-item detection and identification test (R. Doty, *The Smell Identification Test: Administration Manual* 1983: 13-14, Philadelphia: Sensonics, Inc. (1983); A.R. Hirsch et al., *Chemical Senses* 18(5): 570-571 (1993); A.R. Hirsch et al., *Chemical Senses* 17(5): 643 (1992)). The individual can also be evaluated for olfactory capacity (e.g. loss of smell) according to an olfactory threshold test as known and used in the art. Such a test provides a precise magnitude of loss of smell and classifies the individual as normosmic, hyposmic or

anosmic, which is useful in assessing the effectiveness of a particular odorant and/or the required concentration of the odorant to provide a suprathreshold level to effectively reduce migrainous symptoms. According to that test, an odorant substance such as butyl alcohol, phenyl ethyl alcohol, or pyridine, is combined in an odorless liquid medium to provide a series of dilutions, or binary steps, of the odorant. For each successive binary step up the dilution scale, the odorant is present, for example, at one half the concentration of the preceding step. The highest concentration of the odorant usually provides the substance at an irritant level. The individual is presented with the series of dilutions in ascending order, and is asked to compare each dilution step to at least one control stimulus, such as odorless propylene glycol.

Ranges of the average normal threshold for various odorant substances can be found in the art, for example, Amoore and O'Neill, "Proposal for Unifying Scale to Express Olfactory Thresholds and Odor Levels: The "Decismel Scale"," in *Proceedings of the 1988 Air Pollution control Association Annual Meeting*, Paper No. 78.5 (21 pp.), Air and Waste Management Association, Pittsburgh, PA (1988); Amoore and Haotala, "Odor as an Aid to Chemical Safety: Odor Thresholds Compared with Threshold Limit Values and Volatiles for 214 Industrial Chemicals in Air and Water Dilution," *J. Appl. Toxicology* 3(6):272-290 (1983).

In the art, a "normosmic" individual is one who can detect the odor of a substance without irritant sensations when the odorant is presented within the range of its average normal threshold. A "hyposmic" or "microsmic" individual has reduced capacity of the olfactory nerve being able to detect an odorant substance by its odor at a concentration, or decismel level, above that of a normosmic individual yet below its irritant concentration level. An "anosmic" individual is one who has essentially no olfactory nerve capacity being unable to detect the odor of the odorant substance, but has trigeminel nerve function, being able to detect an odorant substance by means of irritant, tingling sensations when it is present at an irritant concentration. A patient who is able to detect pyridine vapor by means of irritant, tingling sensations caused by stimulation of the trigeminel nerve, but who cannot distinguish a pyridine odor at a

lower concentration without such sensation, is considered to be anosmic having no olfactory nerve sensitivity.

The odorant substance is dispensed to a subject in a form that provides a vaporous emission for inhalation. The odorant substance can be administered in a liquid or solid form contained in a capped vessel, by opening a blister pack or scratch-and-sniff odor patch containing microcapsules of the odorant, as a spray from an aerosol or non-aerosol pump-type spray device, by means of a scented cloth, as a nasal spray, as a cologne or a cream, from a pen-like dispenser containing a liquid form of the odorant, and the like. Such a pen-type dispenser can be composed of a dispenser that has a tip impregnated with the odorant; the dispenser preferably contains a liquid form of the odorant, optionally adsorbed to a wicking material. It is preferred that the odorant is provided in a portable dispenser that is easily transportable and readily accessible by a person in need of relief, for example, a blister pack, booklet of scratch-and-sniff odor patches, pen-type dispenser, and the like.

The odorant substance can be packaged as part of a kit in association with a container such as a vial, jar, pouch, bottle, cloth, aerosolizer, blister pack, and the like, that holds an effective amount, or unit dosage amount, of the odorant to increase/decrease vaginal flow when administered to a female individual; and written or other form of instructions (e.g., video or cassette tape) of the use of the odorant to alter vaginal flow. The kit can also include a substance and instructions for testing olfactory capacity for the presence and/or identity of an odorant, and/or olfactory threshold. The various parts of the kit can be packaged separately and contained within a box or other packaging material.

Odorants can be screened for their effectiveness in altering vaginal blood flow by administering the odorant by inhalation in an amount and for a time period effective to alter vaginal blood flow. The effect of an odorant and/or odorant mixture can be assessed and measured objectively by administering a test to measure initial vaginal blood flow, and then re-testing the subject after being given the odorant. The effectiveness of the odorant on the subject to increase or decrease vaginal flow can be

assessed by comparing the amount of vaginal blood flow before and after inhaling the odorant.

The effect of an odorant or mixture of odorants can also be assessed subjectively by interviewing and questioning the female individual as to the effectiveness of the odorant in increasing or decreasing the level of their sexual arousal (e.g., whether they are experiencing an increase or decrease in sexual stimulation) before and after inhaling the odorant substance.

The therapeutic implications of the present method are many. Individual females can benefit by inhaling certain odorants that will enhance or decrease their sexual arousal, and hence, help treat sexual arousal disorders. The use of odorants in increasing or decreasing vaginal blood flow provides a useful therapy that is also easy to administer for those who are in need of enhanced or repressed sexual arousal. The invention will be further described by reference to the following detailed example. This example is not meant to limit the scope of the invention that has been set forth in the foregoing description. Variations within the concepts of the invention are apparent to those skilled in the art. The disclosures of the cited references throughout the application are incorporated by reference herein.

## EXAMPLE

A study was conducted to assess the effect of odorants on vaginal blood flow, a measure of the level of female sexual arousal and excitation. Thirty adult pre-menopausal, perialivatory women volunteered for this IRB approved study. Subjects were 18-40 years old, were not on any prescription or non-prescription medication including oral contraceptives, were literate in English, non-lactating, not actively attempting pregnancy, not smoking for at least one year, consumed less than one drink of alcohol per day, not using cocaine or other illegal drug, and had no genital sexual stimulation by self or their partner for 48 hours prior to the study session. All scored normosmic on the University of Pennsylvania Smell Identification Test.

The subjects had no diseases known to induce autonomic disorders or chemosensory disorders, and were not on medications that produce chemosensory disorders.

**Methods**. After being positioned on the examination table, a vaginal process graphic recording device was applied. The device was a sterile monitoring gauge, a photophlethysmograph, similar in shape to a tampon, which was placed into the vagina. The monitoring device measured pulse pressure which indicates change in blood flow to the vagina. The gauge was hooked up to a computer and changes in pulse strength were recorded on a continual basis.

A three minute period was allowed for acclamation to the experimental environment or a longer duration was allowed until stable baseline measurements were obtained (which measures vaginal bloodflow). A surgical mask untreated with any added odor, was applied over the subject's mouth and nose for one (1) minute. During this time, vaginal blood flow was recorded. After the one-minute measurement was taken, the women were asked if the odor was familiar, if they could identify it, and if they liked it or disliked it. Following this, the mask was removed for a three (3) minute, no odor "washout" period during which blood flow was measured when no mask was in place. This was to eliminate the effect of the odor -- positive or negative -- so that blood flow returned to baseline. In a double-blind, randomized fashion in which neither the subjects nor the test administrators knew which scents were being tested at any given time during the study, ten (10) surgical masks that had been pre-impregnated with different individual odors or odor mixtures were applied in a similar fashion as in the initial blank mask and recorded to obtain in a similar fashion to the original blank mask. After this, another blank mask and recordings were obtained, with the initial and final blank mask used as markers of baseline.

Bloodflow was determined with the farral vaginal photophlethysmograph, and computer-assisted therapy device as per published protocol. All odors were FDA/GRAS approved and impregnated on molded paper 3M surgical masks at

suprathreshold, non-trigeminal levels as determined by an independent panel of the Smell and Taste Treatment Research Foundation. Statistical analysis was performed independently by the University of Illinois, School of Public Health. Statistical significance was timed by P value less than or equal to 0.05. Data was analyzed using non-parametric tests of Signed Rank Test, Wilcoxin Rank Sum Test, and Spearman's Rank Correlation Coefficient. (T. Colton, *Statistics in Medicine*, Little Brown & Co., Boston, MA (1974); E.L. Lehmann, *Nonparametrics: Statistical Methods Based on Ranks*, Holden-Day, New York, NY (1975)).

Each woman was also given a series of tests of olfactory ability. Subjects underwent standardized olfactory testing with the University of Pennsylvania Smell Identification Tests (UPSIT), a 40-question forced choice scratch-and-sniff test in which the person is given four choices for each question and that has been normalized at age and sex. For example, in one question, an odor is presented, and the individual is asked if the odor is pizza, motor oil, peanuts, or lilac. Each subject was also given an odor threshold test, the Pyridine Olfactory Threshold test, a forced-choice test during which bottles containing various concentrations of pyridine, a chemical whose odor resembles scallops. This test evaluates the concentration of the odor that must be present before it is detectable. With this group of tests, olfactory acuity could be established, and those subjects who had a normal sense of smell and those with lesser or no ability to smell.

Subjects also underwent a series of questionnaires regarding demographic data, sexual history data, sexual history and olfactory preference. These included a vaginal bloodflow study questionnaire which queried regarding use of cologne and food hedonics, as well as sexual conduct and behavior. Subjects were questioned as to favorite colognes and whether they or their sexual partner wore a perfume or cologne on a regular basis, favorite and least favorite food, number of sexual partners and encounters in the previous thirty days, sexual preference, and odors that recalled childhood.

The subjects were also questioned about orgasmic functioning, including frequency in the last thirty days and over the previous six months. Through these questions, the number of women who experienced orgasm but did so infrequently, and a group who were multiorgasmic were determined.

The subjects also completed the Sexual Arousal Ability Inventory, a standardized test of accessing ease of arousability on a negative 1 to 5 scale (Hoon, E.F., Hoon, P.W., and Wincze, J.P., The SAI: "An Inventory for the Measurement of Female Sexual Arousability," *Arch. Sex. Behav.* 5:291-300 (1976)), and the Sexual Arousal Ability Inventory which accesses a negative 1 to 5 scale degree of anxiety induced by a variety of sexual activity (Chambles, D.L., and J.L. Lifshitz, "Self-reported Sexual Anxiety and Arousal: The Expanded Sexual Arousability Inventory," *J. Sex. Research* 20:241-254 (1984)). Each activity was rated for its ability to arouse or to inhibit arousal. Participants were asked if particular activities were either very arousing (5) or adversely affected their arousal (-1). The twenty eight questions used to assess sexual behaviors were used to rate sexual anxiety. The participants were asked to rate not only what aroused them (or turned them off) but also what activities would induced feelings of anxiety -- defined as extreme uneasiness or distress. The scale was reversed, meaning the -1 indicated that the activity was relaxing or calming and 5 indicated that the activity was extremely anxiety-producing. For example, circling the number 2 in response to a question meant that the activity sometimes caused anxiety or was slightly anxiety-producing. The range allowed for differences not only among individual women, but for each woman, depending on the setting.

**Results**. The effect of odor on vaginal blood flow was calculated based on changes from the average of the bloodflow measured while the subject was wearing the blank masks. Vaginal blood flow changes are shown in **Tables I-V**, below.

The sources of odorants in the Tables were as follows:

Baby powder = Internatl. Flavors and Fragrances, Inc. (IFF) (#3169-HS)

Banana nut bread = Aromatech (#256454)

Charcoal barbecue smoke = IFF (#2185-HS)

Cherry = Orchidia (# F180075)

Chocolate = Florasynth, Inc. (#A3898)

Cologne = Old Spice®

Cucumber = Aromatech (#256452)

Good N' Plenty® (licorice-based) = Aromatech (#236923)

Lavender = Energy Essentials

Perfume = Chanel No. 5

Pumpkin pie = Florasynth, Inc. Energy Essentials (#AG-6956)

**Table I**, below, shows the average change in vaginal blood flow of the entire group of female test subjects (n=19) when administered individual odorants and odorant mixtures.

**TABLE I**

**AVERAGE % CHANGE IN VAGINAL BLOOD FLOW IN TOTAL GROUP OF FEMALES**

| ODORANT | % CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT) |
|---|---|
| Good N' Plenty® + cucumber | + 13 % |
| Baby powder | + 13 % |
| Pumpkin pie + lavender | + 11 % |
| Baby powder + chocolate | + 4 % |
| Perfume | + 0-1 % |
| Cologne | -1 % |
| Good N' Plenty® | -12 % |
| Charcoal barbecue smoke | - 14 % |
| Cherry | - 18 % |

As a group, several smells impaired arousal. Those odors that had the greatest negative effect, meaning that the baseline blood flow measurement actually decreased, were cherry (18-percent reduction) and charcoal barbecue smoke (14-percent reduction).

Other odors had a lesser effect. Male colognes decreased vaginal flow by 1 percent, and female perfumes increased it by 1 percent. A combination of baby powder and chocolate resulted in a 4-percent increase.

Pumpkin pie and lavender increased vaginal blood flow by 11 percent. The odor that had the greatest effect to induce female sexual arousal was a combination of Good & Plenty® licorice-based odorant and cucumber which increased blood flow by 13 percent.

While the Good & Plenty® licorice-based odorant and cucumber combination was arousing to most women, difference occurred among the participants based on the kinds of sexual behavior and activities preferred. For example, the women could be subgrouped into those who found masturbation arousing and those who did not. **Table II**, below, shows the average change in vaginal blood flow of the subgroup of female individuals who indicated a high sexual arousal with masturbation on the questionnaire. **Table III**, below, shows the average change in vaginal blood flow of the subgroup of female individuals who indicated repulsion or low arousal with masturbation on the questionnaire.

## TABLE II

### FEMALES WITH HIGH AROUSAL WITH MASTURBATION

| ODORANT | % CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT) |
|---|---|
| Good & Plenty® + banana nut bread | + 28 % |
| Good & Plenty® + cucumber | + 22 % |
| Perfume | + 18 % |

## TABLE III

### FEMALES WITH INHIBITION OR LOW AROUSAL WITH MASTURBATION

| ODORANT | % CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT) |
|---|---|
| Baby powder | + 16 % |
| Pumpkin pie + lavender | + 10 % |
| Good & Plenty® | - 20 % |

Among women who reported being extremely aroused by masturbation, every odor tested had an arousing effect. A Good & Plenty® licorice-based odorant and banana-nut bread combination (28-percent increase) and the Good & Plenty® licorice-based odorant and cucumber combination (22 percent) showed the greatest effect. Popular perfumes showed an 18-percent increase in vaginal blood flow, as did baby powder, which was nearly as arousing at a 16-percent increase.

Women who did not find masturbation extremely arousing showed an increase in vaginal blood flow of 16 percent in response to baby powder and a 1-percent response to lavender and pumpkin pie.

The women could also be subgrouped into those who were extremely aroused when a lover manually stimulated here genitals and those who were not. **Table IV**,

below, shows the average percent change in vaginal blood flow of the subgroup of female individuals who indicated that they are positively aroused sexually by partner's finger manipulation of the genitals on the questionnaire. **Table V**, below, shows the average percent change in vaginal blood flow of the subgroup of female individuals who indicated a low to zero to negative level of arousal by partner's finger manipulation of the genitals on the questionnaire.

**TABLE IV**

**FEMALES WHO ARE POSITIVELY AROUSED BY GENITAL FINGER MANIPULATION BY PARTNER**

| ODORANT | % CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT) |
|---|---|
| Good N' Plenty® + cucumber | + 18 % |
| Pumpkin pie + lavender | + 12 % |

**TABLE V**

**FEMALES WHO ARE NEGATIVELY AROUSED BY GENITAL FINGER MANIPULATION BY PARTNER**

| ODORANT | % INCREASE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT) |
|---|---|
| Perfume | - 14 % |
| Cologne | - 14 % |
| Good N' Plenty® + cucumber | - 13 % |

Women who found manual genital stimulation arousing showed a 12-percent increase in vaginal blood flow in response to pumpkin pie and lavender, and averaged an 18-percent increase with the Good & Plenty® licorice-based odorant and cucumber combination.

No odors induced sexual arousal in the women who were not extremely aroused by manual genital stimulation, whereas many odors inhibited arousal, including male colognes and perfumes, both of which decreased blood flow by 14 percent. The Good & Plenty® licorice-based odorant and cucumber combination decreased blood flow by 13 percent in that group.

There were also differences found in response to odors among women who reported being multiorgasmic during at least one-third of their sexual encounters versus those who experienced a single orgasm during their sexual encounters or reported being multiorgasmic less than one-third of the time. Among those women who were frequently multiorgasmic, the inhalation of a baby powder odorant decreased vaginal blood flow (over base line) by about 8%. By comparison, in females who were mono-orgasmic were aroused in response to a baby powder odorant with an average increase of vaginal blood flow by about 15%.

**Discussion**. It has presently been found that certain odors can be administered to a female individual to increase or decrease vaginal blood flow which, in turn, has an impact upon female sexual arousal in both an enhancing and/or an inhibiting way. The results show that an odorant can be administered for inhalation by a female to alter her vaginal blood flow by about -20% to about +30% compared to baseline vaginal blood flow (no odorant given). The administration of odorants provides a non-invasive method of altering vaginal blood which can result in an increase or decrease in the female individual's level of sexual arousal.

As the results indicate, an odorant can be administered to increase vaginal blood flow of a female individual and enhance sexual arousal. The results showed that the most effective odor for female arousal was a combination of food odors. While women's responses to odors are not homogeneous and women respond differently depending on their preferences of sexual activities and behaviors, the licorice-based odorant and cucumber combination was the most effective odor overall.

Individual odorants and odorant mixtures that increased vaginal blood flow by about 10-30%, included a baby powder odorant, a mixture of a licorice-based odorant and banana nut bread odorant, a mixture of a licorice-based odorant and cucumber odorant, a floral-aldehydic perfume fragrance (e.g., Chanel No. 5), a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants. These individual odorants and odorant mixtures were particularly effective in increasing vaginal blood flow in those female individuals who are positively sexually aroused with masturbation or by manual manipulation of the genitals.

Odorants can also be administered to decrease vaginal blood flow of a female individual and the level of sexual arousal. The odorants and odorant mixtures that caused a decrease in vaginal blood flow by about 10-20% included a licorice-based odorant alone, a mixture of a licorice-based odorant and cucumber odorant, a charcoal barbecue meat odorant, a cherry odorant, a men's cologne (e.g., Old Spice), and a floral-aldehydic perfume fragrance (e.g., Chanel No. 5). These odorants and odorant mixtures were particularly effective in reducing vaginal blood flow in those female individuals who were not sexually aroused with masturbation or by touching or manipulation of the genitals by a partner.

Although not intended to limit the invention to a particular theory, one way that the odorants can act on female sexual arousal is through a learned conditioned response. If the odor is one that the female associates with a past experience of being sexually aroused, the odor may induce a sexually arousing mechanism. This could be a primary conditioned response or through secondary effects, for example, by inducing a more positive mood state or relaxed state which may cause females to remove or reduce inhibitions. Positive moods and relaxed states can be achieved either directly through a conditioned response through a learned response paradigm, or through a phenomenon of olfactory evoked nostalgia whereby an odor induces a positive mood state in an individual as a result of recalling the past.

The odorants may also act to enhance female sexual arousal by acting directly on areas of the brain in a more physiological way. For example, the odors may have

stimulated the reticular activating system of the brain which makes one awake and alert. In this alert state, the women may have become more aware of sensory stimuli in the environment, including sexual cues.

In addition, the odors may have acted directly on the brain to reduce anxiety. For example, in one study, people were placed in a coffinlike tube which induced a claustrophobic response. Odors were then added to the environment and their effect was evaluated. The odor of cucumber reduced anxiety and altered participant's perception of space. In a similar way, the odor of cucumber may have reduced anxiety among the women test subjects.

The odorants may also impact upon sexual arousal by inducing a state of risk taking or of generalized pleasure seeking as in seeking food or other pleasure-oriented responses. In addition, the odorants may inhibit associated cortical functioning that would induce a release of the "id" or the underlying limbic system functioning, hence allowing more primitive responses. This has been observed in decorticate animals (e.g., Kluvor-Bucy syndrome) and in humans who have developed marked cortical deficits, such as obese Down's syndrome individuals. Similar responses have been observed in individuals who became more tired, and thus become more easily induced to sexual arousal or eating. Similarly, cortical suppression with alcohol can lead to a lack of discrimination for sexual partners, which may be due to alcohol-induced inhibition of olfactory reception, similar indiscriminate mating as seen in rats.

For women for whom masturbation is extremely arousing, there are two theories about their response. In the study, a monitoring device was in place in the vagina throughout the test. The odors may have acted to change the women's focus of attention and enhanced the perception of touch. The presence or absence of one sensory modality can affect our perception of another. Many people say that they have improved perception of auditory stimuli when they are in total darkness. In the study, the sense of smell may have acted on the tactile sensations produced by the vaginal monitor. Further, since these women were easily sexually excited by touch, the odors may have had an even greater effect in combination with the tactile sensation produced

by the monitoring device; their touch receptors were already conditioned to be more sensitive to tactile stimuli, and the olfactory stimulation further enhanced the perception of touch.

Alternatively, rather than odors increasing awareness of the vaginal monitoring device, the odors may have made the women less aware of the device. For some women, the monitor may have been slightly painful and the odors may have distracted them and, therefore, decreased their discomfort. Or, the odors may have acted physiologically to reduce pain. In a study of individuals who suffered from migraine headaches, the odor of green apple was shown to relieve pain; since pain inhibits sexual arousal, the odors may have acted to reduce the discomfort of the vaginal monitoring device. When there is minimal pain and discomfort, sexual arousal is enhanced.

One explanation for both the positive and negative responses that make anatomic sense is that the odors acted on the septal nucleus which is the erection center of the brain. Animal studies have shown that stimulation of the septal nucleus of the squirrel monkey results in erection, and a direct anatomic connection exists between the olfactory bulb and the septal nucleus. The odors may have acted directly on the septal nucleus to either stimulate or inhibit arousal.

The invention has been described by reference to detailed examples and methodologies. These examples are not meant to limit the scope of the invention. It should be understood that variations and modifications may be made while remaining within the spirit and scope of the invention. The disclosures of the cited references are incorporated by reference herein.

**WHAT IS CLAIMED:**

1. A method for altering vaginal blood flow of a female individual, comprising:

administering to the female by inhalation of an odorant in an amount effective to alter vaginal blood flow.

2. The method of claim 1, wherein the odorant is effective to increase vaginal blood flow of the female individual by about 10-30%.

3. The method of claim 2, wherein the odorant is selected from the group consisting of a baby powder odorant, a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a floral-aldehydic perfume odorant, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants.

4. The method of claim 1, wherein the odorant is effective to increase vaginal blood flow of the female individual by about 4-15%.

5. The method of claim 4, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a baby powder odorant, a mixture of a lavender and pumpkin pie odorant, and a mixture of a baby powder and chocolate odorant.

6. The method of claim 1, wherein the odorant is effective to decrease vaginal blood flow of the female individual by about 10-20%.

7. The method of claim 6, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, a mixture of licorice-based and cucumber odorants, and a floral-aldehydic perfume odorant.

8. The method of claim 6, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.

9. The method of claim 1, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.

10. The method of claim 9, wherein the concentration of the odorant is at about 25-55 decismel units.

11. The method of claim 1, further comprising: having the female individual inhale the odorant for about 1-3 minutes.

12. A method of screening an odorant for altering vaginal blood flow of a female individual, comprising:

administering to the female individual an odorant by inhalation in an amount and for a time period effective to alter vaginal blood flow; and

at least one of: measuring the vaginal blood flow of the female individual before and after administering the odorant; and questioning the female individual as to the effectiveness of the odorant in increasing or decreasing sexual arousal before and after inhaling the odorant substance.

13. The method of screening of claim 12, further comprising, prior to administering the odorant: testing the female individual for olfactory ability.

14. An article of manufacture, comprising, packaged together:

an odorant as recited in claim 1 packaged within a container, wherein the odorant when inhaled by a female individual is effective to alter vaginal blood flow; and

instructions for use of the odorant for altering vaginal blood flow according to the method of claim 1.

15. The article of manufacture according to claim 14, further comprising at least one of the following:

a device for measuring vaginal blood flow of the female individual; and

means for testing olfactory ability in the female individual.

16. The article of manufacture of claim 14, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.

17. The article of manufacture of claim 16, wherein the concentration of the odorant is at about 25-55 decismel units.

18. The article of manufacture of claim 14, wherein the odorant is packaged within a delivery means selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.

19. The article of manufacture of claim 14, wherein the odorant is in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.

20. The article of manufacture of claim 14, wherein the odorant is in the form of a cream or a cologne.

21. The article of manufacture of claim 14, wherein the odorant is in a liquid form contained in a dispenser.

22. The article of manufacture of claim 14, wherein the dispenser has a tip impregnated with the odorant.

23. The article of manufacture of claim 22, wherein the dispenser contains the odorant adsorbed to a wicking material.

## ABSTRACT OF THE DISCLOSURE

A non-invasive method of altering vaginal blood flow in a female individual to augment or lessen sexual arousal is provided. The method involves administering an individual odorant or odorant mixture for inhalation that is sufficient to alter vaginal blood flow of the female by about -20% to about +30% compared to a baseline vaginal blood flow without inhalation of the odorant. Also provided is a method for screening an odorant for its capacity to increase or decrease vaginal blood flow, and an article of manufacture, or kit, containing an odorant and instructions for its use in altering vaginal blood flow.

CERTIFICATION UNDER 37 CFR 1.10 OF MAILING BY "EXPRESS MAIL"

Express Mail Label No: EL008428815 US

Date of Deposit: December 14, 1998

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" on the date indicated above and is addressed to the: Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

By: Kristine M Strodthoff

Name: Kristine M. Strodthoff

MW2-159387-1

Attorney's Docket No.: 054012-0009

**United States Patent Application**
**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR

the specification of which:
(a) [ ] is attached hereto.
(b) [ X ] was filed on December 14, 1998 as Serial No. 09/211,507
for which I solicit a United States patent.

**ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 Code of Federal Regulations § 1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent (see last page attached hereto).

**PRIORITY CLAIM (35 U.S.C. § 119)**

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed, or a provisional application filed under § 111(b) of Title 35 (35 U.S.C. § 119(b)).

[ ] no such applications have been filed.
[ X ] such applications have been filed as follows.

**FOREIGN/PCT or PROVISIONAL APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION, CLAIMING PRIORITY UNDER 35 U.S.C. § 119**

| COUNTRY (OR INDICATE IF PCT) | APPLICATION NUMBER | DATE OF FILING (day, month, year) | PRIORITY CLAIMED UNDER 37 USC § 119 |
|---|---|---|---|
| USA | 60/069,460 | 15-DEC-1997 | [ X ] YES [ ] NO |

**FOREIGN/PCT APPLICATION(S) FILED BEFORE THE PRIORITY APPLICATION(S)**

| COUNTRY (OR INDICATE IF PCT) | APPLICATION NUMBER | DATE OF FILING (day, month, year) | DATE OF ISSUE |
|---|---|---|---|
| | | | |

**PRIORITY CLAIM (35 U.S.C. § 120/365)**

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT International application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material

information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

| U.S. APPLICATION NUMBER | DATE OF FILING (day, month, year) | STATUS (patented, pending, abandoned) |
|---|---|---|
| | | |
| | | |

**POWER OF ATTORNEY**

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Nicholas A. Kees; Reg. No. 29,552
Adam L. Brookman; Reg. No. 32,401
Derek C. Stettner; Reg. No. 37,945
Brian G. Gilpin, Reg. No. 39,997
Kristine M. Strodthoff, Reg. No. 34,259

**SEND CORRESPONDENCE TO:**

Kristine M. Strodthoff
Godfrey & Kahn, S.C.
780 North Water Street
Milwaukee, WI 53202
Tel. (414) 273-3500

**DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**Full name of first inventor**

Alan (GIVEN NAME) R. (MIDDLE INITIAL OR NAME) Hirsch (FAMILY (OR LAST NAME))

Country of Citizenship: USA

Residence: 7 VERNON TRAIL, RIVERWOODS, IL 60015

Post Office Address: Same

Inventor's signature: Alan R Hirsch Date 2/9/99

**Full name of second inventor**

(GIVEN NAME) (MIDDLE INITIAL OR NAME) (FAMILY (OR LAST NAME))

Country of Citizenship: _____

Residence: _____

Post Office Address: _____

Inventor's signature: _____ Date _____

RULE 56 (37 U.S.C. §1.56)

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office. This includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information that is material to the patentability of a canceled or withdrawn claim need not be submitted if the information is not material to the patentability of any of the remaining claims. There is no duty to submit information that is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by 37 C.F.R. §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.